

required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995; 66 FR 38788, July 25, 2001]

### Subpart D—Clinical Toxicology Test Systems

#### § 862.3030 Acetaminophen test system.

(a) *Identification*. An acetaminophen test system is a device intended to measure acetaminophen, an analgesic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

(b) *Classification*. Class II.

#### § 862.3035 Amikacin test system.

(a) *Identification*. An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.

(b) *Classification*. Class II.

#### § 862.3040 Alcohol test system.

(a) *Identification*. An alcohol test system is a device intended to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

(b) *Classification*. Class II.

#### § 862.3050 Breath-alcohol test system.

(a) *Identification*. A breath-alcohol test system is a device intended to measure alcohol in the human breath. Measurements obtained by this device

are used in the diagnosis of alcohol intoxication.

(b) *Classification*. Class I.

#### § 862.3100 Amphetamine test system.

(a) *Identification*. An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

(b) *Classification*. Class II.

#### § 862.3110 Antimony test system.

(a) *Identification*. An antimony test system is a device intended to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.

(b) *Classification*. Class I.

#### § 862.3120 Arsenic test system.

(a) *Identification*. An arsenic test system is a device intended to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood. Measurements obtained by this device are used in the diagnosis and treatment of arsenic poisoning.

(b) *Classification*. Class I.

#### § 862.3150 Barbiturate test system.

(a) *Identification*. A barbiturate test system is a device intended to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose and in monitoring levels of barbiturate to ensure appropriate therapy.

(b) *Classification*. Class II.

#### § 862.3170 Benzodiazepine test system.

(a) *Identification*. A benzodiazepine test system is a device intended to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam,